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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,113	03/19/2001	Gabriele Nelles	450117-03033	2990

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EXAMINER	
HON, SOW FUN	

ART UNIT	PAPER NUMBER
1772	12

DATE MAILED: 10/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

AS-12

Office Action Summary	Application No.	Applicant(s)	
	09/744,113	NELLES ET AL.	
	Examiner	Art Unit	
	Sow-Fun Hon	1772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 February 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29 and 52-97* is/are pending in the application.

4a) Of the above claim(s) *1-29 and 52-73* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *74-79,90-91,93-94,96-97* is/are rejected.

7)☒ Claim(s) *80,92 and 95* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Amendment

Allowable Subject Matter

1. Claims 80, 92, 95 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Withdrawn Rejections

2. The 35 U.S.C. 112, 2nd paragraph, 102(b) and 103(a) rejections to claims 30-51 in Paper # 9 (mailed 02/12/03) have been withdrawn due to Applicant's cancellation of clarifications and amendments in Paper # 11 (filed 07/18/03).

New Rejections

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 74-97 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific azosilane monomer (page 11, lines 1-15), does not reasonably provide enablement for any other "monomeric" material. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Applicant states that "the most important criterion which any of the above materials have to fulfill is the low toxicity towards cells, the capability of undergoing switching under physiological or nearly physiological conditions, preferably 36.5 °C in buffered aqueous solution". Applicant is respectfully reminded that there is a multitude of alignment materials belonging to the inorganic, organic and hybrid classes of monomeric materials, and that physiological compatibility such as low toxicity towards cells and physiological activity such as the capability of switching under physiological conditions are unpredictable.

MPEP 2164.03 states that in cases involving unpredictable factors, such as most chemical reactions and physiological activity, more [disclosure] may be required. *In re Fisher, 427F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970)* (contrasting mechanical and electrical elements with chemical reactions and physiological activity). See also *In re Wright, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)*; *In re Vaeck, 947 F.2d 488, 496, 20 USPQ2d 1438, 1445 (Fed. Cir. 1991)*. This is because it is not obvious from the disclosure of one species, what other species will work.

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 74-97 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear how the basic structure further limits the substrate structure. Furthermore, it is unclear how the neuron, alignment layer and liquid crystal layer are positioned relative to each other.

Claim Rejections - 35 USC § 103

7. Claims 74-79, 81-89, 93-94, 96-97 are rejected under 35 U.S.C. 103(a) as being unpatentable over Georger, Jr. et al.

Georger, Jr. et al. is directed to a basic substrate which contains a patterned surface for the selective neurite outgrowth (of cells in the definition of neuron geometry formation) (column 9, lines 20-50). Prior art is cited in which a large neuron is positioned over and adhered to substrate mounted electrodes. The microsensor has a transducer which stimulates the cell adhering to it. Georger, Jr. et al. teaches an embodiment wherein a liquid crystal or conductive polymer acts as the transducer for the microsensor, and has a surface area coated with cell adhesion promoter which permits adhesion of a cell on the transducer. The transducer is used to stimulate the cell (column 10, lines 40-65). The basic structure comprises a glass substrate (column 12, lines 55-70).

Georger, Jr. et al. teaches the alignment (placement) of cells within lithographically defined physical barriers such as microtrenches or wells, and onto substrate-embedded microelectrodes (column 15, lines 55-70). Thus although Georger, Jr. et al. fails to specifically teach that the liquid crystal acting as the transducer is aligned by an alignment layer on the basic substrate, one of ordinary skill in the art would have known that the microtrenches provide alignment of the liquid crystal transducer which provides the electrical stimulation for neuron cell growth.

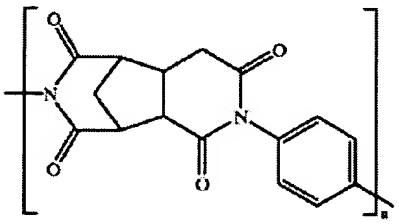
Since Georger et al. also teaches polyester (polyethylene terephthalate), polyamide, polyurethane, polymethacrylate, azosilane (silazane) as the patterned film (column 5, lines 25-50), and since the polymeric layer alignment of liquid crystal is well known in the art, it would

have been obvious to one of ordinary skill in the art to have used those materials as alignment layers for the liquid crystal transducer. Polymers normally have amorphous regions unless the chains are able to form perfect crystals.

Georger, Jr. et al. fails to teach that the alignment layer is made out of monomeric or polymeric materials having liquid crystalline and amorphous elements, wherein the polymeric material is selected from the group consisting of polyester, polypeptide, polyacrylamide, polyvinyl alcohol, polyacrylate, polymethacrylate, polyurea and polyamide.

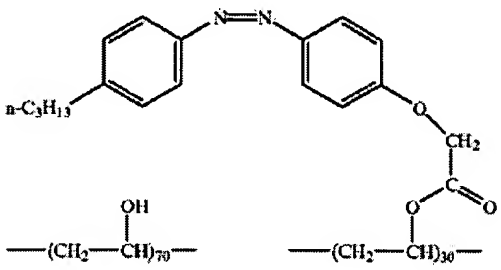
Kawata has a glass support (column 5, lines 55-60) with an alignment layer formed with a chromophore (photochromic compound) which includes azobenzene (column 6, lines 5-50) of thickness 100 nm to 5000 nm (μm) (column 7, lines 60-65). The chromophore is reacted (chemically bound) to a polymer which is a polyvinyl alcohol (column 7, lines 10-40). A polyimide with a homolog variation of the claimed structure (a phenyl instead of a biphenyl on one side) (column 15, lines 5-20) is shown below:

(Polymide)



and a polyvinyl alcohol is reacted with the azobenzene chromophore shown below wherein the vinyl alcohol repeat unit is an insert on the bottom left :

(Photo isomerization polymer)



The azobenzene attached to the polyvinyl alcohol via the ester linkage yields an azobenzene sidechain liquid crystalline polyester as seen above, and a longer alkyl chain on the very tip of the azobenzene is a homolog. P6a12, P68a10, P10a10, P8a12 and P10a12 are homologs where the x-para-substituent varies in terms of the number of methylene groups, n varies in terms of the number of methylene groups in the flexible side chain spacer and m varies in the number of methylene groups in the acidic part of the main chain.

Kawata teaches that the alignment defect for an alignment layer formed with the azobenzene chromophore is lower than one formed without (column 17, lines 1-50).

Both Kawata and Georger, Jr. et al. are directed to a film for alignment on a substrate, and are thus analogous art.

Therefore it would have been obvious to one of ordinary skill in the art to have used the azobenzene sidechain liquid crystalline polyester taught by Kawata as the alignment surface with microtrenches in the invention of Georger, Jr. et al. in order to obtain a substrate structure for neurite outgrowth with higher alignment precision due to lower alignment defect.

8. Claims 90-91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Georger, Jr. et al. in view of Kawata as applied to claims 74-79, 81-89, 93-94, 96-97 above, and further in view of Grainger et al.

Georger et al. has been discussed above and teaches the substrate structure for neurite outgrowth with at least one neuron ontop of said basic structure and the liquid crystal. Georger et al. fails to teach the alignment layer under the liquid crystal.

Kawata demonstrates that liquid crystal aligned by an alignment layer under it is well known in the art, and teaches an azobenzene chromophore added onto the side chain of the polymer comprising the alignment layer, but fails to teach that polypeptides are equivalent to the polyimide and polyvinyl alcohol materials used as the alignment polymer.

Grainger et al. teaches the formation of an anisotropic polymeric film on a substrate to impart anisotropic properties to the substrate (column 1, lines 1-25). The polymers recited are polyimide, polyamide, polyacrylate and polymethacrylate (column 2, lines 45-65) and polyvinyl alcohol (column 12, lines 50-65). The polymer is taught to also comprise polypeptide, a liquid crystal molecule, a polar adhesive group and a chromophore (column 5, lines 1-20), wherein poly(benzyl)glutamate is an example of a polypeptide (column 11, lines 30-60). Grainger et al. teaches that the polymer is bound across the surface of a substrate in a predetermined alignment (pattern) as points of attachment for cell growth (column 15, lines 10-20) thus acting as an alignment layer on the substrate for cell growth.

Since Grainger et al. is directed to a film for alignment, Kawata is directed to a film for alignment, and Georger, Jr. et al. is directed to a film for alignment, they are analogous art.

Since Grainger et al. demonstrates equivalency of poly(benzyl)glutamate with polyimide and polyvinyl alcohol, it would have been obvious to one of ordinary skill in the art to have used the polypeptide materials of Grainger et al. as alternate polymers in polymer alignment layer of

Kawata, for use to align the liquid crystal transducer in the invention of Georger, Jr. et al. in order to obtain an alternate basic substrate for neurite outgrowth.

Response to Arguments

9. Applicant's arguments with respect to claims 30-51 have been considered but are moot in view of Applicant's cancellation of said claims, and the new ground(s) of rejection.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication should be directed to Sow-Fun Hon whose telephone number is (703)308-3265. The examiner can normally be reached Monday to Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached on (703)308-4251. The fax phone number for the organization where this application or proceeding is assigned is (703)872-9311.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0661.

SH
Sow-Fun Hon
10/17/03

HAROLD PYON
SUPERVISORY PATENT EXAMINER
1772
10/18/03